Clinical and Translational Science Awards

National Center for Research Resources

The National Institutes of Health (NIH) has launched a new national consortium designed to spur the transformation of clinical and translational research in the United States, so that new treatments can be developed more efficiently and delivered more quickly to patients.

Drawing from experience of the NIH Roadmap for Medical Research and extensive community input, the Clinical and Translational Science Awards (CTSAs) program will create a definable academic home for the discipline of clinical and translational science at institutions across the country.

Specifically, this program, which the National Center for Research Resources (NCRR) is leading on behalf of the NIH Roadmap, encourages the development of novel methods and approaches to clinical and translational research, enhances informatics and technology resources, and improves training and mentoring to ensure that new investigators can navigate the increasingly complex research system. To create this home, the program allows for local flexibility so that each institution can determine whether to establish a Center, Department, or Institute (C/D/I) in clinical and translational science.

The CTSA RFA will be issued annually. The current RFA calls for submissions by January 17, 2007. The second round of awards are anticipated in September 2007.

CTSA RFA: http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-07-002.html

The first 12 academic health centers (AHCs) to receive the CTSAs were announced in October 2006. An additional 52 AHCs received planning grants to help them prepare applications to join the consortium. When fully implemented in 2012, about 60 institutions will be linked together to energize the discipline of clinical and translational science. For more information about the announcement, visit http://www.ncrr.nih.gov/clinicaldiscipline.asp.

Key Elements of CTSA

- **Development of Novel Clinical and Translational Methodologies:** To sustain intellectual exploration, faculty members could pursue their funded research in areas such as new phenotyping methods that are more objective and quantifiable; the development of biomarkers for research purposes; clinical trial design research; clinical informatics for longitudinal studies; development of research devices and methods that could be used in patients' homes; predictive toxicology in human populations; and ethics research specific to populations rather than specific trials.
- **Pilot and Collaborative Translational and Clinical Studies:** An applicant can request support to fund Pilot and Collaborative clinical research projects that 1) allow clinical and translational trainees or researchers to generate preliminary data for submission of a research grant application; 2) seek to improve clinical design, biostatistics, clinical research ethics, informatics, or regulatory pathways; 3) develop new technologies; or 4) others as defined by the applicant.
- **Biomedical Informatics:** The effective implementation of this program depends largely on communication within C/D/Is and with all collaborating organizations. Applicants should consider both internal, intra-institution and external interoperability to allow for communication among C/D/Is and the necessary research partners, such as government, clinical research networks, pharmaceutical companies, and research laboratories.

- **Design, Biostatistics, and Clinical Research Ethics:** Research in these three areas is quite limited so applicants are encouraged to develop innovative and creative research programs that bridge these functions with other CTSA activities. Topics for research might include limiting risk to participants, preventing bias, improving enrollment, capturing appropriate data, developing design and analysis plans for studies of unique populations or very small numbers of subjects, informed consent, and issues related to diseases with limited treatment options.

- **Regulatory Knowledge and Support:** Support for research teams will promote the protection of human subjects and facilitate regulatory compliance. Applicants are encouraged to be innovative at all levels of clinical research regulation including the provision of integrated training, services, or tools for protocol and informed consent authoring and translation, adverse event reporting, safety and regulatory management and compliance, etc. Institutions could develop best practices that reduce or remove institutional impediments to clinical and translational research and, through dissemination and sharing, enhance inter-institutional collaborations.

- **Participant and Clinical Interactions Resources:** These resources could provide an environment to promote participation in clinical and translational research and help determine the most efficient and effective ways to interact with participants in clinical trials. Examples of resources might include the recruitment of research participants, the provision of in-patient, out-patient, or community-based exam rooms, medical vans, temporary research participant recruitment/enrollment sites, research nurses, research coordinators, phlebotomists, scheduling services, and services for research specimen collection and shipping. Applicants should describe a plan to recruit investigators, especially those early in their professional careers, and make the availability of Participant and Clinical Interactions resources known throughout the institution and medical catchments area.

- **Community Engagement:** The intent of this component is to foster collaborative partnerships and enhance public trust in clinical and translational research, facilitating the recruitment of research participants from the community. Approaches could include engagement of both the public and community providers, and establishing long-term relationships with community-based groups such as voluntary and professional organizations, schools, women's health groups, faith-based groups, and housing organizations. Resources might include community outreach and cultural sensitivity training for institutional clinical and translational researchers, community and provider education and outreach, development of software to facilitate the collaboration of community practitioners, and communication outlets such as newsletters and internet sites.

- **Translational Technologies and Resources:** Depending on the needs of the C/D/I, resources such as mass spectrometry, imaging, ultrasound, positron emission tomography, gene expression, proteomics, translational cell and gene therapies could be supported.

- **Research, Education, Training, and Career Development:** A key component of a CTSA will be one or more graduate degree-granting and post graduate programs in clinical and translational science. C/D/Is will train investigators from diverse disciplines, such as medicine, pediatrics, surgery, dentistry, nursing, and pharmacology, as well as study coordinators, project managers, and other key clinical research personnel relevant to clinical and translational sciences. Topics include clinical research design, epidemiology, biostatistics, pharmacology, biomedical informatics, ethics, behavioral science, engineering, and law.

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